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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/500,324
Filing Date: June 28, 2004
Appellant(s): PAOLINI ET AL.

/Phil Wiest/
Examiner, Art Unit 3761

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/11/07 appealing from the Office action mailed 4/2/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,561,997	WEITZEL et al.	05-2003
4,894,164	POLASCHEGG	01-1990
6,582,387	DEREK et al.	06-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 26 and 28-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weitzel et al. (US 6561997) over Polaschegg (4,894,164), and further in view of Derek et al. (US 6,582,387).

2. With respect to Claim 26, Weitzel et al. disclose an apparatus for controlling an extracorporeal blood circuit comprising an access branch 58 that is connected to at least one blood treatment element 48 and a return branch 70 having one end connected to an outlet of at least blood treatment element 20. Both branches are connected to a patient 100 (see Figure 1). The apparatus comprises a sensor/control unit that is capable of "...precise control over fluid flow rate, pressure within the circuit, and temperature of fluid in the circuit" (Column 3, Lines 57-59), and a temperature regulating device (8, 34). Because "temperature ... can be precisely controlled" (Column 4, Lines 16-20), it is inherent that the apparatus comprises a control unit connected to the temperature regulating devices (8, 34). Furthermore, Weitzel et al. disclose that the heat exchanger 8 functions to keep the blood at a physiological temperature (Column 6, Lines 16-19), thus functioning according to a first temperature (actual blood temperature) and a reference temperature (preferred physiological blood temperature).

Weitzel et al., however, does not disclose that the temperature sensor is located in the access branch, upstream of all blood treatment devices, nor does it disclose that the temperature regulating device 8 is located downstream of all blood treatment elements to form a heat exchanger directly before blood reenters the patent.

Polaschegg discloses a blood treatment apparatus comprising a temperature sensor 206 located in the access branch 220 and upstream of all blood treatment devices (see Figure 1). The temperature sensor 206 is used to record the temperature of the blood leaving the body for use as a reference temperature to be used by control unit 208 (Column 7, Lines 1-9). Therefore, it would have been obvious to one skilled in

the art at the time of invention to combine the apparatus of Weitzel et al. with the temperature sensor placement of Polaschegg in order to measure the true temperature of blood leaving the body for use as a reference temperature for controlling the heat exchanger 8. By measuring the true blood temperature, the reference temperature/ desired blood output temperature will be closer to true physiological temperature of the patient rather than an estimated reference value.

Derek et al. discloses a blood treatment apparatus wherein a heat exchanger may be placed within the return tube 50 (Column 10, Lines 7-11), which is downstream of all blood treatment elements (see Figure 2). It is obvious that blood will cool down (or heat up, depending on the surrounding air temperature) when removed from the body to be treated in a blood treatment apparatus. Because of this, it would be desirable to place the heat exchanger as far downstream and as close to the patient as possible, such that minimal temperature change occurs before blood is returned to the patient. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the blood treatment apparatus of Weitzel et al. with the heat exchanger placement of Derek et al. in order to minimize temperature change before blood reenters the body.

3. With respect to Claims 28 and 29, Weitzel et al. further disclose that the regulating device comprises a heat exchanger 8 that is connected to the circuit in order to control flow temperature, and a line 16 for conveying a fluid. The fluid being conveyed is capable of being heated to a temperature lying within a specified range

about 37°C (Column 6, Lines 15-19), as per instant Claim 28. Regarding Claim 29, the heat exchanger can be "...at least partially surrounding any portion of the intake line" (Column 6, Lines 20-21).

4. With respect to Claim 30, the extracorporeal blood circuit is connected to a pump 52 which conveys fluid along the extracorporeal blood circuit, a line 70 for conveying fluid, and a sensor which detects the operating state of said pump. Regarding Claim 31, Weitzel et al. disclose expansion chambers 62 and 64 and a return branch 70 that is located downstream from the expansion chambers. Examiner interprets that "expansion chambers" are the same as the replacement fluid bags 62 and 64. Said replacement fluid bags serve to "...infuse [fluids] into the conduit 58 with a pump 56 to replace blood volume lost as a waste product 10" (Column 4, Lines 57-58).

5. With respect to Claims 32-35, Weitzel et al. disclose a blood treatment element formed by a filter 48, and at least one expansion chamber 62 and 64. Furthermore, Weitzel et al. disclose that the filter is a hemofilter 48, but that "...and blood treatment device can be used in place of the hemofilter 48. For example, but without limitation, a dialyzer or a plasma filter can be used to separate a filtrate component from the blood" (Column 5, Lines 10-13). Additionally, a dialyzer flowing from dialysis system 194 (see Figure 4) can be used to separate filtrate components from the blood (see Column 5, Line 10-13).

6. With respect to Claims 36 and 37, Weitzel et al. disclose that the control unit regulates the blood temperature of the extracorporeal blood in the line as a function of the blood temperature and the temperature of the body (37°C) (Column 6, Lines 16-19).

This is inherent because Weitzel et al. disclose that the heat exchanger 8 functions to keep the blood at a physiological temperature (Column 6, Lines 16-19), thus functioning according to a first temperature (actual blood temperature) and a reference temperature (preferred physiological blood temperature). The controller will inherently function by calculating the difference between the actual temperature of the blood and a reference temperature, as per Claim 37. Furthermore, it is inherent that all sensors function by recording data at predetermined intervals of time, and a specific interval of time is not disclosed by Applicant. Said "predetermined intervals" are determined by the controller to which the sensor is attached, and are limited by the ability of the specific sensor.

7. With respect to Claims 38-43, Weitzel et al. disclose a control method for an extracorporeal blood circuit comprising an access branch 58 and a return branch 70 both of which being attached to at least one blood treatment element (20, 48) (see Figure 1). Both the access line and the return line are connected to the patient 100. The method comprises measuring and regulating a blood temperature in the extracorporeal blood circuit through the use of circuits that "...will provide tightly controlled pressure, flow, and/or temperature through the circuit" (Column 12, Lines 45-46). The blood temperature is regulated by the heat exchanger 8, which is located downstream from blood treatment element 48.

Weitzel et al., however, does not disclose measuring blood temperature using a sensor that is located in the access branch, upstream of all blood treatment devices, nor

does it disclose heating the blood with a temperature regulating device 8 located downstream of all blood treatment elements.

Polaschegg discloses a blood treatment method comprising measusing blood temperature with a sensor 206 located in the access branch 220 and upstream of all blood treatment devices (see Figure 1). The temperature sensor 206 is used to record the temperature of the blood leaving the body for use as a reference temperature to be used by control unit 208 (Column 7, Lines 1-9). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the method of Weitzel et al. with the temperature sensor placement of Polaschegg in order to measure the true temperature of blood leaving the body for use as a reference temperature for controlling the heat exchanger 8. By measuring the true blood temperature, the reference temperature/ desired blood output temperature will be closer to true physiological temperature of the patient rather than an estimated reference value.

Derek et al. discloses a blood treatment method and apparatus wherein a heat exchanger may be placed within a return tube 50 (Column 10, Lines 7-11), which is downstream of all blood treatment elements (see Figure 2). It is obvious that blood will cool down (or heat up, depending on the surrounding air temperature) when removed from the body to be treated in a blood treatment apparatus. Because of this, it would be desirable to heat blood at a point as far downstream and as close to the patient as possible, such that minimal temperature change occurs before blood is returned to the patient. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the blood treatment method of Weitzel et al. with the heat exchanger

placement of Derek et al. in order to minimize temperature change before blood reenters the body.

8. Regarding Claims 39 and 40, the temperature of the blood is regulated in the heat exchanger 8 as a function of the actual blood temperature and the reference temperature. The heat exchanger 8 "...functions to keep blood at a physiological temperature such that any metabolic functions that the treatment device 20 carries out can be accomplished" (Column 6, Lines 16-19). Thus, the heat exchanger will correct the temperature of the blood according to the difference between the blood and the reference temperature. Heat will be added if this differential is positive, and removed if the differential is negative.

9. With respect to Claims 44-46, Weitzel et al. disclose a method wherein fluid is conveyed along the heat exchanger 8 through the connected tubing. The fluid is heated to within a specified range about 37°C. Blood is conveyed through the heat exchanger, as well as the rest of the circuit, by means of a pump. When the pump is not turned on, fluid in the heat exchanger will remain at a temperature equal to the reference temperature. Additionally, the Weitzel et al. discloses that the reference temperature is capable of being varied. The control system allows for "...precise control over fluid flow rate, pressure within the circuit, and temperature of fluid in the circuit" (Column 3, Lines 56-59).

10. With respect to Claims 47-50, Weitzel et al. disclose that the method of conveying fluid is used for a hemodialysis treatment that utilizes a hemofilter.

Additionally, Weitzel discloses that any type of blood treatment device such as a dialyzer can be used to separate a filtrate component from the blood. This includes hemofiltration filters and hemodialysis filters through which blood and dialysate flow. See column 5, line 11 of the specification. The extracorporeal blood circuit also comprises expansion chambers 62 and 64 supplied with a replacement fluid (see column 4, lines 56-58).

(10) Response to Argument

With respect to Claims 26 and 38 Applicant argues that Weitzel, Polaschegg, and Derek do not disclose all the elements of the claimed apparatus, and that there is not motivation to combine the references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, Applicant quotes the Non-final rejection mailed on 9/27/06 on several occasions when arguing against the Weitzel patent. These arguments are moot because that rejection has been replaced by a 103(a) rejection in view of the amended claims.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is common knowledge to those of ordinary skill in the art that the placement of temperature sensors at the inlet and outlet of the circuit (as taught by Polaschegg) improves temperature control, and that the placement of a heat exchanger at the outlet of the circuit will prevent heat loss after the temperature of the blood is adjusted to a physiologic temperature.

Specifically, as stated in the Final Rejection, Wietzel discloses temperature control by detecting a sensed temperature of the fluid going through the circuit and correcting the temperature to a reference temperature (physiological temperature) (see Weitzel: Column 3, Lines 56-59; Column 4, Lines 16-20; Column 6, Lines 16-19; and Column 12, Lines 56-64). Therefore, if the sensed blood temperature is 20°C, the heat exchanger will heat the blood such that it is within the normal physiological range. Although Weitzel does not disclose that the blood temperature is sensed at a position in the arterial branch as it is drawn from the patient, Polaschegg provides sufficient motivation to suggest doing so (see Polaschegg: Column 7, Lines 1-9).

Additionally, as discussed above, Derek discloses heating *outgoing* blood in the *return* line (Column 10, Lines 7-11). It is the examiner's opinion that this means that the heat exchanger is placed at or near the outlet of the circuit (i.e. after the treatment element). As shown in Figure 5, the return line (where the heat exchanger is placed) is

located after the treatment element and flows back into the patient. Derek anticipates the need to keep blood at a physiological temperature, especially when t is returned to the body.

With respect to Claim 45, applicant argues that Weitzel does not disclose a method of keeping the blood temperature equal to the reference temperature when the pump is not operating. This argument has not been found persuasive. The heat exchanger of Weitzel is arranged such that it functions to keep blood at a physiological temperature at all times (Column 6, Lines 16-19).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Phil Wiest/

Examiner, Art Unit 3761

Conferees:

/Tatyana Zalukaeva/ /Heather Shackelford/

Supervisory Patent Examiner, Art Unit 3761